

(iii) The evidence was not submitted as required by § 12.85.

(2) Items of written evidence are to be submitted as separate documents, sequentially numbered, except that a voluminous document may be submitted in the form of a cross-reference to the documents filed under § 12.85.

(3) Written evidence excluded by the presiding officer as inadmissible remains a part of the administrative record, as an offer of proof, for judicial review.

(d) Testimony, whether on direct or on cross-examination, is admissible as evidence unless a participant objects and the presiding officer excludes it.

(1) The presiding officer may exclude oral evidence as inadmissible only if—

(i) The evidence is irrelevant, immaterial, unreliable, or repetitive; or

(ii) Exclusion of part or all of the evidence is necessary to enforce the requirements of this part.

(2) If oral evidence is excluded as inadmissible, the participant may take written exception to the ruling in a brief to the Commissioner, without taking oral exception at the hearing. Upon review, the Commissioner may reopen the hearing to permit the evidence to be admitted if the Commissioner determines that its exclusion was erroneous and prejudicial.

(e) The presiding officer may schedule conferences as needed to monitor the program of the hearing, narrow and simplify the issues, and consider and rule on motions, requests, and other matters concerning the development of the evidence.

(f) The presiding officer will conduct such proceedings as are necessary for the taking of oral testimony, for the oral examination of witnesses by the presiding officer on the basis of written questions previously submitted by the parties, and for the conduct of cross-examination of witnesses by the parties. The presiding officer shall exclude irrelevant or repetitious written questions and limit oral cross-examination to prevent irrelevant or repetitious examination.

(g) The presiding officer shall order the proceedings closed for the taking of oral testimony relating to matters specified in § 10.20(j)(2)(i) (a) and (b). Such closed proceedings will be con-

ducted in accordance with § 10.20(j)(3). Participation in closed proceedings will be limited to the witness, the witness' counsel, and Federal Government executive branch employees and special government employees. Closed proceedings will be permitted only for, and will be limited to, oral testimony directly relating to matters specified in § 10.20(j)(3).

#### § 12.95 Official notice.

(a) Official notice may be taken of such matters as might be judicially noticed by the courts of the United States or of any other matter peculiarly within the general knowledge of FDA as an expert agency.

(b) If official notice is taken of a material fact not appearing in the evidence of record, a participant, on timely request, will be afforded an opportunity to show the contrary.

#### § 12.96 Briefs and arguments.

(a) Promptly after the taking of evidence is completed, the presiding officer will announce a schedule for the filing of briefs. Briefs are to be filed ordinarily within 45 days of the close of the hearing. Briefs must include a statement of position on each issue, with specific and complete citations to the evidence and points of law relied on. Briefs must contain proposed findings of fact and conclusions of law.

(b) The presiding officer may, as a matter of discretion, permit oral argument after the briefs are filed.

(c) Briefs and oral argument are to refrain from disclosing specific details of written and oral testimony and documents relating to matters specified in § 10.20(j)(2)(i)(a) and (b), except as specifically authorized in a protective order issued under § 10.20(j)(3).

#### § 12.97 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section and in §§ 12.35(b), 12.45(e), 12.93(f), and 12.99(d), when an interlocutory appeal is specifically authorized by this subpart, rulings of the presiding officer may not be appealed to the Commissioner before the Commissioner's consideration of the entire record of the hearing.